"A Continuing Investigation into the Fungal Meningitis Outbreak and Whether It Could Have Been Prevented"
Opening Statement of the Honorable Tim Murphy
Chairman, House Energy & Commerce Oversight & Investigations Subcommittee
April 16, 2013

The Subcommittee is here today because 53 people died from a pain medication manufactured by the New England Compounding Center (NECC). Those patients trusted that the steroid injected into their spine or their joints to relieve chronic pain was perfectly safe because of the confidence our nation's healthcare providers place in the Food and Drug Administration. But that drug was contaminated with fungus, a form of mold that attacks bone and nerves.

More than 700 people received these lethal injections. Today, they are living with the unbearable horror of not knowing whether they will survive. They must spend weeks in the hospital, missing work, holidays, and time with family. They must take large doses of morphine to ease the pain.

Each day is lived under the deadly threat of an infection that could reach their brains and kill them.

This outbreak is one of the worst public health disasters in our country's history. It is a terrible tragedy and an epic failure. Sadly, the Food and Drug Administration, which is supposed to protect the public, has spent its time passing blame and hiding behind judicial robes rather than taking any responsibility.

At our hearing last November, Commissioner Hamburg told this Committee that the FDA faced "complex" issues in taking enforcement action against the New England Compounding Center.

Here is the truth: this outbreak begins with NECC illegally shipping 17,000 vials of supposedly sterile drugs without patient prescriptions. The FDA s insists it could not tell the difference between a corner-store compounder who makes cough syrup for a child, and a massive manufacturer illegally shipping into 23 states.

This Committee has discovered the agency had information that should have spurred it to act and stop this rogue outfit from continuing to operate as an illegal manufacturer of sterile medication.

This outbreak is not "complex" nor was it a surprise. Neither NECC nor its sister company, Ameridose, were operating in the shadows. They were under the nose of the FDA for a decade. FDA field staff and FDA headquarters repeatedly received complaints about NECC's numerous transgressions. They even considered additional inspections and enforcement actions. Ten years of warning signs, alarm bells, and flashing red lights were deliberately ignored. Complaints came from patients, nurses, pharmacists, doctors, pain clinics, hospitals, drug companies, drug distributors and even confidential company informants. About the only healthcare entity that didn't seem worried was FDA headquarters. Ultimately, the FDA knew NECC was breaking the law but chose to do nothing.

In 2007, the FDA received complaints from patients getting epidural injections of an injectable steroid manufactured by NECC. FDA knew long ago that this very NECC product hospitalized patients with meningitis-like symptoms — these complaints led to FDA's first inspection of NECC. This time, there's no evidence that FDA even bothered to inform the state or contact the company over this issue.

In 2011, a representative from the Institute of Safe Medication Practices contacted the FDA about an Ameridose medication.

The complaint read, quote, "As a practicing pharmacist, I am shocked that such a product would be allowed to be distributed for use in the United States." FDA officials found the product to be "extremely dangerous." A member of FDA's compounding team wrote: "And they should further warn that this bag should not be directly infused to the patient. This is unbelievable! I think this is a disaster waiting to happen."

After FDA headquarters approved — then rejected — sending a Warning Letter to Ameridose in 2009, the current Director of FDA's New England District Office angrily informed other enforcement officials with FDA: "I've told our [Investigations Branch] to not bother inspecting compounding pharmacies if we aren't going to act on the violations."

FDA's primary mission is to protect the public health from unsafe drug products. On numerous occasions, the agency confronted a choice in dealing with NECC and Ameridose: take action to protect patients or wait. Repeatedly, the FDA made a conscious decision to do nothing. In particular, under your watch, Dr. Hamburg, the FDA put enforcement actions against NECC and Ameridose on hold in 2011 and through 2012, because the FDA lawyers wanted to wait until finishing a revision of a guidance document.

During this inspection holiday, 53 people died.

At the last hearing Congressmen Terry, Scalise, and I asked Dr. Hamburg where in the law it said FDA could not act. The FDA did not answer our question. We now know that there was nothing in the law that prevented the FDA from acting because in the last few weeks before this hearing, the FDA has conducted a highly visible campaign of inspections. This flurry of well-publicized activity exposes the FDA's charade. The agency cannot argue it lacked authority to inspect NECC and Ameridose, but now, after the outbreak, has the authority to conduct these inspections.

No law has changed. The only change is the FDA decided to act.

During our November hearing, Dr. Lauren Smith of the Massachusetts Department of Public Health recognized her agency could have done things differently. She did not hide behind ongoing investigations, lawsuits, or limited authority. Instead, she admitted that her agency had moved too slowly, and that if they had acted quickly in July 2012, it could have prevented about a third of the deadly drug from being shipped. She took immediate personnel actions as a result of these conclusions.

The hope of this committee is that we will hear admissions from the FDA that reflect decisive leadership — an admission of what went wrong internally to delay inspections, warnings, and actions. What I fear we will hear this morning is continued litany of excuses, bureaucratic talk, and blame on outside organizations.

For the families of those who died, and those who are still sick, we will not stop in our effort to get answers and fix this problem.

I now recognize my distinguished colleague from Colorado, Ranking Member DeGette, for her opening statement.